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Attorney Dkt. No. 092633-0107

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James FULLER
Title: NUCLEIC ACID CONSTRUCTS
Appl. No.: 10/575,087
International Filing Date: 10/11/2004
371(c) Date:
Examiner: Michelle S. Horning
Art Unit: 1648
Confirmation Number: 8717

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In the Office Action dated March 24, 2010, the Examiner required restriction of the claims as follows:

Group I: Claims 85-103, 109-113, 116-121 and 124-128, drawn to a nucleic acid construct.

Group II: Claims 104, 105, 114, 122 and 129, drawn to a method of obtaining expression in mammalian cells.

Group III: Claims 106-108, 115, 123 and 130, drawn to a method of nucleic acid immunization.

The Office Action alleges that the “application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1” because the claims allegedly “lack the same or corresponding special technical feature” as required under PCT Rule 13.2. (Office Action at pages 2-3). The Office Action further asserts that “applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.” (Office Action at page 2).

In response, Applicant hereby elects Group I, claims 85-103, 109-113, 116-121 and 124-128, with traverse. Applicant respectfully contends, contrary to the Office Action assertion, that the three groups of claims are linked by a special technical feature as required by PCT Rule 13.2. Moreover, the pending claims are directed to “a product and process of use of said product” as defined under 37 C.F.R. § 1.475(b). As such, the claims meet the unity of invention requirements, and reconsideration and withdrawal of the restriction between Groups I, II and III is respectfully requested.

The Office Action further asserts that “the application contains claims directed to more than one species of the generic invention,” and that “[t]hese species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1” (Office Action at page 3). The species as set forth in the Office Action are presented below:

- A. A specific leader sequence (claim 86, iii);
- B. A specific enhancer sequence (claim 86, iv);
- C. A specific heterologous intron (claim 86, v);
- D. A specific polyadenylation sequence (claim 87, ii);
- E. A specific polyadenylation signal (claim 87, iii);

- F. A specific signal peptide (claim 87, iv);
- G. A specific antigen or polypeptide encoded by the construct (claims 92-95);
- H. A gold or tungsten particle (claim 97);
- I. A specific polypeptide of the additional construct (claim 103);
- J. A specific route of construct delivery (claim 105, ii);
- K. A method of immunization against a pathogen, allergy or cancer (claim 108);
- L. How the components of the constructs are operably linked.

In response, Applicant elects the following species:

- A. A non-translated leader sequence that is SEQ ID NO: 5.
- B. An enhancer sequence that is SEQ ID NO: 8.
- C. A heterologous intron that is the rat insulin intron A sequence.
- D. A polyadenylation sequence that is the rabbit β -globin gene.
- E. A polyadenylation signal that is SEQ ID NO: 10.
- F. A signal peptide that is human tissue plasminogen activator signal peptide (hTPAsp).
- G. An antigen or polypeptide encoded by the construct that is HBsAg.
- H. A gold particle.

- I. A polypeptide of the additional construct that is ADP ribosylating bacterial subunit A and B.
- J. A route of delivery comprising transdermal particle delivery.
- K. A method of immunizing against cancer.
- L. How the components are operably linked – it unclear to the Applicants what options the Examiner has identified.

With respect to Species L, “how the components are operably linked,” Applicants are unclear as to what options the Examiner has identified and how best to respond to this particular requirement. Applicants note that “operably linked” is defined in the specification on page 16 of PCT/GB2004/004279 (paragraph [0124] of U.S. Pub. No. 2008/0160048). To the extent an election must be made to be fully responsive to this Office Action, Applicants respectfully assert that they assume that by electing a species from each of groups A-K, Applicants have also elected a species from of group L. If this assumption is incorrect, Applicants respectfully request further clarification of this species and an additional period of time in which to reply.

Once the elected species is found patentable, the Examiner should consider the full scope of the pending claims.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

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